



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,530	01/23/2004	Minoru Sano	NPR-135	5543
20374	7590	05/05/2006	EXAMINER	
KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006			MCCORKLE, MELISSA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,530

Applicant(s)

SANO ET AL.

Examiner

Melissa A. McCorkle

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Tachikawa et al (US 2005/0119620). Tachikawa discloses a prefilled syringe comprising a shoulder portion 21 provided with a luer tip (near 24) arranged to be connected to an injection needle at a tip thereof; a barrel 2 closed by the shoulder portion and having an open proximal end (fig 1); and a gasket 3 inserted adjacent to the open proximal end of the barrel in a fluid-tight manner while being freely slideable

(abstract), a medication being contained inside the barrel 100, wherein the barrel has a multilayer structure [0054] in which an innermost and an outermost layer is sandwiched by the innermost layer and the outermost layer and is composed of at least one layer made of a resin excelling in a barrier property, and further wherein the intermediate layer is formed up to a vicinity of a surface of the tip of the luer tip, and is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion of the gasket inserted in the barrel (fig 1).

3. Tachikawa also discloses a prefilled syringe comprising a shoulder portion provided with a luer tip arranged to be connected to an injection needle at a tip thereof; a barrel closed by the shoulder portion 21 and having an open proximal end (fig 1); and a gasket 3 inserted adjacent to the open proximal end of the barrel in a fluid-tight manner while being freely slideable (abstract), a medication being contained inside the barrel, wherein the barrel has a multilayer structure in which an innermost and an outermost layer are both made of a polyolefin resin [0054], and an intermediate layer is sandwiched by the innermost layer and the outermost layer and is composed of at least one layer made of a resin exelling in a barrier property, and further wherein an end of the intermediate layer in a cylindrical wall portion of the barrel is formed up to a rim of the shoulder portion; the shoulder portion formed with the polyolefin resin has a thickness sufficient to exert a barrier property, and the luer tip is sealed by a cap having a barrier property (fig 3).

Response to Arguments

Art Unit: 3763

4. Applicant's arguments with respect to claims 1 and 3 have been considered but are moot in view of the new ground(s) of rejection.

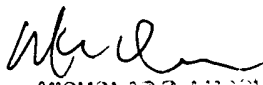
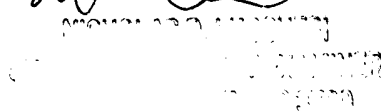
5. It is also pointed out to applicant that portions of the claims appear to be product-by-process, and it should be noted that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle
Examiner
Art Unit 3763